

## **THE CLAIMS**

### **WE CLAIM:**

1. An apparatus for delivering a biologically active material to a body lumen comprising:  
a catheter having a distal portion and a proximal portion;  
a balloon, having an outer surface, disposed at the distal portion of the catheter; and  
a plurality of micro-needles disposed upon the outer surface of the balloon, wherein the micro-needles are capable of contacting the body lumen to deliver the biologically active material to the body lumen; the micro-needles are selected from the group consisting of micro-needles having an exterior surface having at least one gutter disposed along the longitudinal axis of the micro-needles to allow the biologically active material to be delivered along the gutter or micro-needles capable of being ruptured; and said balloon has an interior compartment for containing the biologically active material.
2. The apparatus of claim 1, wherein said catheter has a first lumen therethrough; said interior compartment is in fluid communication with the first lumen; and said micro-needles each have a lumen in fluid communication with the interior compartment of the balloon to allow the biologically active material to be delivered through the lumens of the micro-needles to the body lumen.
3. The apparatus of claim 2, wherein the first lumen of the catheter is used for both inflating the balloon and delivering the biologically active material.
4. The apparatus of claim 2, wherein the first lumen is used for delivering the biologically active material, and said catheter has a second lumen for inflating the balloon.
5. The apparatus of claim 2, wherein the balloon further has an inflation compartment for inflating the balloon which is in fluid communication with the inflation lumen.
6. The apparatus of claim 4, wherein said catheter has a third lumen in fluid communication with the interior compartment for delivering a second biologically active material.

7. The apparatus of claim 6, wherein the catheter has a fourth lumen for blood perfusion.
8. The apparatus of claim 2, wherein the interior compartment is used for both inflating the balloon and delivering the biologically active material.
9. The apparatus of claim 1, wherein the micro-needles have a diameter between about 10 nm and about 100  $\mu\text{m}$ .
10. The apparatus of claim 1, wherein the micro-needles have a length between about 1  $\mu\text{m}$  and about 1 mm.
11. The apparatus of claim 10, wherein the length is between about 10  $\mu\text{m}$  and about 500  $\mu\text{m}$ .
12. The apparatus of claim 11, wherein the length is between about 30  $\mu\text{m}$  and about 200  $\mu\text{m}$ .
13. The apparatus of claim 1, wherein there are more than about ten (10) micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.
14. The apparatus of claim 13, wherein there are between about  $1 \times 10^2$  and about  $1 \times 10^6$  micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.
15. An apparatus for delivering a biologically active material to a body lumen, comprising:
  - a catheter having a distal portion and a proximal portion;
  - a balloon, having an outer surface, disposed at the distal portion of the catheter; and
  - a plurality of micro-needles disposed upon the outer surface of the balloon, wherein the micro-needles are capable of contacting the body lumen to deliver the biologically active material to the body lumen, wherein the balloon has an interior compartment for containing the biologically active material, wherein the micro-needles each have a lumen in fluid communication with the interior compartment, and

said micro-needles allow the biologically active material to be delivered from the interior compartment through the lumens of the micro-needles to the body lumen.

16. The apparatus of claim 15, wherein a second biologically active material is coated onto the outer surface of the balloon.

17. The apparatus of claim 15 wherein the catheter has a first lumen therethrough; and wherein the interior compartment is in fluid communication with the first lumen.

18. The apparatus of claim 15, wherein the outer surface of the balloon is part of a balloon wall and wherein the catheter has a first lumen therethrough; and wherein the interior compartment is in fluid communication with the first lumen, and said balloon wall contains a plurality of pores whereby the biologically active material is delivered to the body lumen through the pores.

19. The apparatus of claim 18 wherein the balloon wall comprises an inner layer and an outer layer, and wherein said plurality of pores are located in the outer layer.

20. The apparatus of claim 19 wherein biologically active material is located between the inner layer and the outer layer.

21. The apparatus of claim 15, wherein the micro-needles have a diameter between about 10 nm and about 100  $\mu\text{m}$ .

22. The apparatus of claim 15, wherein the micro-needles have a length between about 1  $\mu\text{m}$  and about 1 mm.

23. The apparatus of claim 22, wherein the length is between about 10  $\mu\text{m}$  and about 500  $\mu\text{m}$ .

24. The apparatus of claim 23, wherein the length is between about 30  $\mu\text{m}$  and about 200  $\mu\text{m}$ .

25. The apparatus of claim 15, wherein there are more than about ten (10) micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.

26. The apparatus of claim 25, wherein there are between about  $1 \times 10^2$  and about  $1 \times 10^6$  micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.

27. An apparatus for delivering a biologically active material to a body lumen comprising:

a catheter having a distal portion and a proximal portion;  
a balloon, having an outer surface, disposed at the distal portion of the catheter; and  
a plurality of micro-needles disposed upon the outer surface of the balloon,

wherein the micro-needles are capable of contacting the body lumen to deliver the biologically active material to the body lumen; the outer surface of the balloon is part of a balloon wall; and the micro-needles are disposed upon a plate, which is attached to said balloon wall in a manner such that the micro-needles project through the balloon wall.

28. The apparatus of claim 27, wherein the plate is attached to the balloon in a manner such that the micro-needles are capable of being retracted when the balloon is deflated and projected through the balloon wall when the balloon is expanded.

29. An apparatus for delivering a biologically active material to a body lumen comprising:

(a) a catheter having a distal portion, a proximal portion and a first lumen therethrough;

(b) a balloon disposed at the distal portion of the catheter, wherein the balloon has an interior compartment in fluid communication with the first lumen of the catheter; the balloon has an outer surface having a plurality of micro-needles disposed thereon; and said micro-needles have a lumen in fluid communication with the interior compartment and wherein the micro-needles are capable of being ruptured; and

(c) a triggering source, wherein the triggering source ruptures the micro-needles when activated to deliver the biologically active material from the interior compartment of the balloon through the micro-needle lumens to the body lumen.

30. The apparatus of claim 29, wherein the balloon outer surface is part of a balloon wall, and the micro-needles are disposed upon a plate attached to the balloon wall in a manner such that the micro-needles project through the balloon wall.

31. The apparatus of claim 29, wherein the triggering source is disposed at the proximal portion of the catheter.

32. The apparatus of claim 29, wherein the triggering source is selected from the group consisting of a shockwave, ultrasound energy and energy source for delivering a detachable coil.

33. The apparatus of claim 32, wherein the triggering source is a shockwave.